

**UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**WALTER McGILL and DONNA McGILL,  
h/w,**

*Plaintiff,*

**v.**

**ACTAVIS, INC.,  
WATSON PHARMACEUTICALS, INC.,  
PFIZER, INC., AND  
PHARMACIA & UPJOHN CO.,**

*Defendants.*

**CLASS ACTION COMPLAINT  
AND DEMAND FOR JURY TRIAL**

**Case No.**

**CLASS ACTION COMPLAINT FOR PERSONAL INJURY AND DEATH**

Plaintiffs Walter and Donna McGill, h/w for themselves and other similarly situated, by and through the undersigned counsel, through their Class Action Complaint hereby allege against Actavis, Inc., Watson Pharmaceuticals, Inc., (hereinafter “AndroDerm Defendants” or collectively “Actavis”) and Pfizer, Inc., and Pharmacia & Upjohn Co. (hereinafter “Depo Testosterone Defendants” or collectively “Pfizer”) the following:

**INTRODUCTION**

1. This case involves the prescription drugs AndroDerm and Depo Testosterone, which is manufactured, sold, distributed, marketed and promoted by Defendants as a testosterone replacement therapy.

2. Defendants, respectively, misrepresented that AndroDerm and Depo Testosterone is safe and effective treatment for hypogonadism or “low testosterone,” when in fact the drugs cause serious medical problems, including life-threatening cardiac events, strokes, and thrombolytic events.

3. Defendants and other unnamed pharmaceutical corporations involved in the manufacture, sale, distribution, marketing and promotion of testosterone replacement therapy products collectively engaged in aggressive direct-to-consumer and physician promotion, marketing and advertising to create and expand a market for testosterone replacement therapy including Defendants' AndroDerm and Depo Testosterone products and further engaged in an aggressive unbranded "disease awareness" campaign to alert men that they might be suffering from "Low T."

4. As a result of this "disease mongering," as termed by Dr. Adriene Fugh-Berman of Georgetown University Medical Center, individuals diagnosed with Low T has increased exponentially. This has directly related to AndroDerm and Depo Testosterone's sales increasing to over several hundred million dollars.

5. However, consumers of AndroDerm and Depo Testosterone was misled as to the drug's safety and efficacy, and as a result have suffered injuries including life-threatening cardiac events, strokes, and thrombolytic events.

#### **PARTIES**

6. Plaintiffs Walter McGill and Donna McGill ("Plaintiff") is residents of Carnegie, Pennsylvania.

7. Defendant Actavis, Inc. ("Actavis") is a corporation organized and existing under the laws of New Jersey with its principal place of business at 400 Interpace Parkway, Parsippany NJ 07054 and at all times relevant to this Class Action Complaint, was engaged in the business of designing, testing, studying, researching, evaluating, endorsing, formulating, compounding, manufacturing, producing processing, assembling, inspecting distributing marketing, labeling,

promoting, advertising, packaging, selling, prescribing, or otherwise placing AndroDerm in the stream of interstate commerce of the United States, including Pennsylvania.

8. Defendant Watson Pharmaceuticals, Inc. (“Watson”) is a corporation organized and existing under the laws of the state of New Jersey and maintains its principal place of business at 400 Interpace Parkway, Parsippany NJ 07054 and at all times relevant to this Class Action Complaint, was engaged in the business of designing, testing, studying, researching, evaluating, endorsing, formulating, compounding, manufacturing, producing processing, assembling, inspecting distributing marketing, labeling, promoting, advertising, packaging, selling, prescribing, or otherwise placing AndroDerm in the stream of interstate commerce of the United States, including Pennsylvania.

9. Defendant Pfizer, Inc. (“Pfizer”) is a corporation organized and existing under the laws of the state of New York and maintains its principal place of business at 235 East 42<sup>nd</sup> Street, New York NY 10017 and at all times relevant to this Class Action Complaint, was engaged in the business of designing, testing, studying, researching, evaluating, endorsing, formulating, compounding, manufacturing, producing processing, assembling, inspecting distributing marketing, labeling, promoting, advertising, packaging, selling, prescribing, or otherwise placing Depo Testosterone in the stream of interstate commerce of the United States, including Pennsylvania.. and at all times relevant to this Class Action Complaint, was engaged in the business of designing, testing, studying, researching, evaluating, endorsing, formulating, compounding, manufacturing, producing processing, assembling, inspecting distributing marketing, labeling, promoting, advertising, packaging, selling, prescribing, or otherwise placing Depo Testosterone in the stream of interstate commerce of the United States, including Pennsylvania.

10. Defendant Pharmacia & Upjohn Co. ("Pharmacia") is a corporation organized and existing under the laws of the state of New York and maintains its principal place of business at 235 East 42<sup>nd</sup> Street, New York NY 10017 and at all times relevant to this Class Action Complaint, was engaged in the business of designing, testing, studying, researching, evaluating, endorsing, formulating, compounding, manufacturing, producing processing, assembling, inspecting distributing marketing, labeling, promoting, advertising, packaging, selling, prescribing, or otherwise placing Depo Testosterone in the stream of interstate commerce of the United States, including Pennsylvania.. and at all times relevant to this Class Action Complaint, was engaged in the business of designing, testing, studying, researching, evaluating, endorsing, formulating, compounding, manufacturing, producing processing, assembling, inspecting distributing marketing, labeling, promoting, advertising, packaging, selling, prescribing, or otherwise placing Depo Testosterone in the stream of interstate commerce of the United States.

#### **JURISDICTION AND VENUE**

11. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds \$150,000.00, exclusive of interest and costs, and because complete diversity exists between the parties, as Plaintiff is a citizen of Pennsylvania, which is different from the states where Defendants is incorporated and have their principal places of business.

12. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

13. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because Defendants is subject to personal jurisdiction in accordance with 28 U.S.C. § 1391(c) and because a substantial part of the events giving rise to Plaintiff's claims occurred in this jurisdiction.

14. Pursuant to Rule 23 of the Federal Rules of Civil Procedure, plaintiff seeks class certification of a class of all persons who reside in the United States, or their Estates, Administrators or other legal representatives, heirs or beneficiaries, who used AndroDerm and Depo Testosterone who have who have suffered personal injury or death from the ingestion. Included in the class is dependents and others entitled to recover under applicable Wrongful Death and/or Survival Statutes.

15. This class seeks damages for personal injury and wrongful death.

### **GENERAL ALLEGATIONS**

16. This action is for damages and other relieve brought on behalf of the class by Plaintiff, Walter McGill, who was prescribed and supplied with, received and who has taken and applied the prescription drugs AndroDerm and Depo Testosterone, as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by Defendants. This action seeks, among other relief, general and special damages and equitable relief in order to enable Plaintiff to treat and monitor the dangerous, severe and life-threatening side effects caused by these drugs.

17. Defendants' wrongful acts, omissions, and fraudulent misrepresentations caused Plaintiff's and the class' injuries and damages.

18. At all times herein mentioned, the Defendants was engaged in the business of, or was successors in interest to, entities engaged in the business of research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or

selling the prescription drugs AndroDerm and Depo Testosterone for the use and application by Plaintiff and members of the class.

19. At all times herein mentioned, Defendants was authorized to do business within the state of Pennsylvania, where Plaintiff resides.

20. At all times herein mentioned, the officers and directors of Defendants participated in, authorized, and directed the production and promotion of the aforementioned product when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said product, and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiff and the class.

21. Plaintiff files this lawsuit within the applicable limitations period of first suspecting Defendants' medication caused the appreciable harm sustained by Plaintiff. Plaintiff and the class could not, by the exercise of reasonable diligence, have discovered the wrongful cause of Plaintiff and the class' injuries at an earlier time because the injuries was caused without and when theirs injuries was discovered, their cause was unknown to Plaintiff and the class. Plaintiff and members of the class did not suspect, nor did they have reason to suspect, that Plaintiff and the class had been injured, the cause of the injuries, or the tortious nature of the conduct causing the injuries, until less than the applicable limitations period prior to the filing of this action.

22. Additionally, Plaintiff and the class was prevented from discovering this information sooner because Defendants and other unnamed pharmaceutical companies misrepresented and continue to misrepresent to the public, and the medical community, that the drugs AndroDerm, Depo Testosterone and other testosterone prescription drugs is safe and free

from serious side effects, and Defendants have fraudulently concealed facts and information that could have led Plaintiff and the class to discover a potential cause of action.

### **OVERVIEW**

23. Hypogonadism is a specific condition of the sex glands, which in men may involve the diminished production or nonproduction of testosterone.

24. In or about 1999, it was estimated that hypogonadism was estimated to affect approximately “one million American men.

25. In 2000, pharmaceutical companies involved in testosterone replacement therapy estimated that the market was “four to five million American men.” By 2003, the number increased to “up to 20 million men.” However, a study published in the Journal of the American Medical Association (“JAMA”) in August 2013 entitled “Trends in Androgen Prescribing in the United States, 2001-2011” indicated that many men who get testosterone prescriptions have no evidence of hypogonadism. For example, one third of men prescribed testosterone had a diagnosis of fatigue, and one quarter of men did not even have their testosterone levels tested before they received a testosterone prescription.

26. Defendants and other unnamed pharmaceutical corporations involved in the manufacture, sale, distribution, marketing and promotion of testosterone replacement therapy products collectively coordinated a massive marketing, promotional and advertising campaign designed to convince men that they suffer from low testosterone. Defendants and the other companies orchestrated a national disease awareness media blitz that purported to educate male consumers about the signs of low testosterone. The marketing campaign consisted of television advertisements, promotional literature placed in healthcare providers’ offices and distributed to users, and online media.

27. The coordinated marketing, promotion and advertising suggest that various symptoms often associated with other conditions may be caused by low testosterone and encourage men to discuss testosterone replacement therapy with their doctors if they experienced any of these “symptoms.” These “symptoms” include listlessness, increased body fat, and moodiness—all general symptoms that is often a result of aging, weight gain, or lifestyle, rather than low testosterone.

28. Since the FDA approved AndroDerm and Depo Testosterone respectively, Defendants and other unnamed pharmaceutical corporations have also sought to convince primary care physicians that low testosterone levels is widely under-diagnosed, and that conditions associated with normal aging could be caused by low testosterone levels.

29. While running their disease awareness campaign, Defendants Watson and Actavis promote their product AndroDerm as an easy to use, transdermal patch testosterone replacement therapy. Defendants Watson and Actavis contrast their product’s transdermal patch as convenient with less risk of spreading testosterone to others like competitor testosterone under arm gels like Androgel.

30. Defendants successfully created a robust and previously non-existent market for their drug. Defendants and other unnamed pharmaceutical corporations involved in the manufacture, sale, distribution, marketing and promotion of testosterone replacement therapy products collectively spent millions if not \$100 million in promoting testosterone replacement therapy and to convince millions of men to discuss testosterone placement with their doctors, and consumers and physicians relied on Defendants’ promises of safety and ease.

31. Millions was also spent by Defendants and other unnamed pharmaceutical corporations on the unbranded marketing, advertising and promotion. Defendants and other



unnamed pharmaceutical corporations involved in the manufacture, sale, distribution, marketing and promotion of testosterone replacement therapy products collectively had sales over \$2 Billion in 2013. Sales of replacement therapies have more than doubled since 2006, and is expected to triple to \$5 billion by 2017, according to forecasts by Global Industry Analysts. Shannon Pettypiece, *Is Testosterone Drugs the Next Viagra?*, May 10, 2012, Bloomberg Businessweek, *available at*: <http://www.businessweek.com/articles/2012-05-10/is-testosterone-drugs-the-next-viagra>.

32. The marketing program sought to create the image and belief by consumers and physicians that low testosterone affected a large number of men in the United States and that the use of testosterone replacement products like AndroDerm and Depo Testosterone is safe for human use, even though Defendants knew these statements to be false, and even though Defendants had no reasonable grounds to believe them to be true.

33. There have been a number of studies concluding that testosterone therapy causes a sudden increase in hematocrit, hemoglobin and estradiol, and associating its use with increased the risk of heart attacks and strokes and blood clots. Defendants knew or in the exercise of reasonable care should have known that their respective products, AndroDerm and Depo Testosterone was defectively designed, unreasonable dangerous in normal use, and highly likely to cause injury or death, but it failed to provide adequate warnings about these known risks.

#### **FACTUAL ALLEGATIONS COMMON TO ALL CAUSES OF ACTION**

34. The Food and Drug Administration approved Depo Testosterone in July, 1979 and approved AndroDerm in September, 1995.

35. Depo Testosterone is an intramuscular injection, containing testosterone cypionate which is the oil-soluble 17 (beta)-cyclopentylpropionate ester of the androgenic hormone testosterone.

36. AndroDerm is a testosterone transdermal system designed to deliver testosterone continuously for 24 hours following application to intact, non-scrotal skin (e.g., back, abdomen, thighs, upper arms and the active ingredient in the system is testosterone.

37. Testosterone is a primary androgenic hormone responsible for normal growth, development of the male sex organs, and maintenance of secondary sex characteristics.

38. The hormone plays a role in sperm production, fat distribution, maintenance of muscle strength and mass, and sex drive.

39. In men, testosterone levels normally begin a gradual decline after the age of thirty.

40. The average testosterone levels for most men range from 300 to 1,000 nanograms per deciliter of blood. However, testosterone levels can fluctuate greatly depending on many factors, including sleep, time of day, and medication. Resultantly, many men who fall into the hypogonadal range one day will have normal testosterone levels the next.

41. AndroDerm and Depo Testosterone may produce undesirable side-effects to patients who use the drug, including but not limited to, myocardial infarction, stroke, deep vein thrombosis, pulmonary embolism and death.

42. In some patient populations, AndroDerm and Depo Testosterone use may increase the incidence of myocardial infarctions and death by over 500%.

43. Secondary exposure to testosterone can cause side effects in others. In 2009 the FDA issued a black box warning for AndroGel prescriptions, advising patients of reported

virilization in children who was secondarily exposed to the gel. Testosterone may also cause physical changes in women exposed to the drug and cause fetal damage in pregnant women who come into secondary contact with AndroGel. AndroGel is marketing as minimizing this risk of secondary exposure with the tag line "Beyond the Gel."

44. Defendants' marketing strategy along with that of and other unnamed pharmaceutical corporations involved in the manufacture, sale, distribution, marketing and promotion of testosterone replacement therapy products collectively has been to aggressively market and sell their products by misleading potential users about the prevalence and symptoms of low testosterone and by failing to protect users from serious dangers that Defendants knew, or should have known, would result from use of its products.

45. Defendants successfully marketed their respective products, AndroDerm and Depo Testosterone by undertaking a "disease awareness" marketing campaign. This campaign sought to create a consumer perception that low testosterone is prevalent amount U.S. men and that symptoms previously associated with other physical and mental conditions, such as aging, stress, depression, and lethargy was actually attributable to "Low-T."

46. Defendants' and other unnamed pharmaceutical corporations involved in the manufacture, sale, distribution, marketing and promotion of testosterone replacement therapy products collectively engaged in an advertising program that sought to create the image and belief by consumers and their physicians that the use of AndroDerm and Depo Testosterone and other testosterone replacement products was safe methods of alleviating their symptoms, had few side effects and would not interfere with their daily lives, even though Defendants knew or should have known these to be false. The Defendants had no reasonable grounds to believe them to be true.

47. Defendants purposefully downplayed, understated and outright ignored the health hazards and risks associated with using AndroDerm and Depo Testosterone. Defendants and other unnamed pharmaceutical corporations involved in the manufacture, sale, distribution, marketing and promotion of testosterone replacement therapy products collectively deceived potential AndroDerm and Depo Testosterone users by relaying positive information through the press, including testimonials from retired professional athletes, and manipulating hypogonadism statistics to suggest widespread disease prevalence, while downplaying known adverse and serious health effects.

48. Defendants concealed material relevant information from potential AndroDerm and Depo Testosterone users and minimized user and prescriber concern regarding the safety of AndroDerm and Depo Testosterone.

49. In particular, in the warnings Defendants give in their commercials, online and print advertisements, Defendants fail to mention any potential cardiac or stroke side effects and falsely represents that Defendants adequately tested AndroDerm and Depo Testosterone for all likely side effects.

50. As a result of Defendants' advertising and marketing, and representations about its product, men in the United States pervasively seek out prescriptions for AndroDerm and Depo Testosterone. If Plaintiff had known the risks and dangers associated with AndroDerm and Depo Testosterone, Plaintiff would not have used AndroDerm and Depo Testosterone and consequently would not have been subject to its serious side-effects.

**SPECIFIC FACTUAL ALLEGATIONS**

51. Plaintiff Walter McGill, was approximately 39 years of age when he was prescribed and used AndroDerm and Depo Testosterone for symptoms he attributed to low testosterone.

52. The AndroDerm and Depo Testosterone he used caused physical and emotional impairment, which affected his personal and professional life. These impairments included, but was not limited to the development of a myocardial infarction.

53. Prior to using AndroDerm and Depo Testosterone, Plaintiff had no history of developing myocardial infarction.

54. As a result of the injuries sustained by Mr. McGill, his wife, suffered injury in the form of loss of consortium and companionship with her husband.

55. Plaintiffs have and will sustain significant general and special damages, including medical expenses, lost wages, diminished economic horizons, loss of support, loss of love, affection, and companionship, and other items of recoverable damages for which they seek maximum recovery as a matter of law.

56. Had Defendants properly disclosed the risks associated with the use of their Plaintiffs and the class would have avoided the risk of injury, including but not limited to the strokes, either not using testosterone replacement therapy at all, severely limiting the dosage and length of use, and/or by closely monitoring the degree to which the drugs was adversely affecting his health.

**CLASS ACTION ALLEGATIONS**

57. Plaintiff brings this class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of himself and all other similarly situated on behalf the following classes of persons as defined in paragraph 25 below,

58. This first class is defined and described as follows:

All male persons who reside in the United States, or their Estates, Administrators or other legal representatives, heirs or beneficiaries, who used AndroDerm and who have suffered personal injury or death caused by AndroDerm Included in the class is dependents and others entitled to recover under applicable Wrongful Death and/or Survival Statutes. This class seeks damages for personal injury and wrongful death. Excluded from the Class is the Defendant, including any parent, subsidiary, affiliate or controlled person of the defendant and their officers, directors, agents or employees and members of their immediate families. Also excluded from the Class is the judicial officer presiding over the litigation and members of his/her immediate family.

59. AndroDerm was widely prescribed and has been used by millions of men. The members of the class is so numerous that joinder is impracticable and would involve thousands of individual actions.

60. Plaintiff, Walter McGill is a member of the Class he seeks to represent.

61. There is questions of law and fact common to the Class including, but not limited to:

- a. Whether AndroDerm was and is unsafe for human use;
- b. Whether defendant designed, manufactured and/or marketed AndroDerm with knowledge that it was a dangerously defective product;
- c. Whether defendant acted negligently in marketing and selling AndroDerm;
- d. Whether defendant conducted, either directly or indirectly, adequate testing of AndroDerm;

- e. Whether defendant failed to adequately warn consumers of the adverse health hazards caused by using AndroDerm;
- f. Whether defendant falsely and fraudulently misrepresented in their advertisements, promotional materials and other materials, among other things, the safety of using AndroDerm;
- g. Whether defendant knowingly omitted, suppressed or concealed material facts about the unsafe and defective nature of AndroDerm from governmental regulators, the medical community and/or the consuming public;
- h. Whether defendant's post-marketing safety and surveillance system exists, and if so, was designed and implemented in a reasonable manner;
- i. Whether defendant designed and manufactured a drug that was dangerously defective because its use leads to or poses a substantial increased risk of the existence of potentially dangerous side effects, including, but not limited to, heart attack, stroke and blood clots;
- j. Whether defendant knew or should have known that the ingestion of AndroDerm leads to or poses a substantial increased risk of side-effects;
- k. Whether defendant continued to manufacture, label, license, market, distribute, promote and/or sell the drug, AndroDerm, notwithstanding its knowledge of the drug's dangerous nature and side-effects;
- l. Whether the warnings and information defendant provided with AndroDerm was adequate in warning of the potential hazards resulting from its use;
- m. Whether defendant engaged in unconscionable and/or deceptive business practices and conduct;

- n. Whether the Class has been injured by virtue of Defendant's negligence, recklessness, and/or unconscionable and/or deceptive business practices and conduct;
- o. Whether ingestion of AndroDerm causes an increased risk of side-effects; and,
- p. Whether defendant earned substantial profits as a result of their sale of AndroDerm.

62. These and other questions of law and/or fact is common to the Class and predominate over any question affecting only individual class members.

63. The claims of the class representatives is typical of the claims of the Class in that the named representatives and the members of the Class ingested AndroDerm and was injured thereby.

64. The Plaintiff will fairly and adequately represent and protect the interests of the members of the Class. Plaintiff has retained counsel competent and experienced in complex class actions and products liability litigation. Plaintiff has no known interests which is adverse to the interests of the other members of the Class. The interests of the plaintiff and the Class they seek to represent is aligned because of their ingestion of AndroDerm and their consequential increased risk of the existence of the side effects caused by AndroDerm.

65. Class certification is also appropriate under Fed.R.Civ.P. Rule 23(b)(3) because common issues of law and fact relative to the design, manufacture and marketing of AndroDerm predominate over individual issues. A class action is superior to other available methods for the fair and efficient adjudication of this litigation since individual joinder of all members of the Class is impracticable.



66. This second class is defined and described as follows:

All male persons who reside in the United States, or their Estates, Administrators or other legal representatives, heirs or beneficiaries, who used Depo Testosterone and who have suffered personal injury or death caused by Depo Testosterone Included in the class is dependents and others entitled to recover under applicable Wrongful Death and/or Survival Statutes. This class seeks damages for personal injury and wrongful death. Excluded from the Class is the Defendant, including any parent, subsidiary, affiliate or controlled person of the defendant and their officers, directors, agents or employees and members of their immediate families. Also excluded from the Class is the judicial officer presiding over the litigation and members of his/her immediate family.

67. Depo Testosterone was widely prescribed and has been used by millions of men.

The members of the Class is so numerous that joinder is impracticable and would involve thousands of individual actions.

68. Plaintiff, Walter McGill is a member of the Class he seeks to represent.

69. There is questions of law and fact common to the Class including, but not limited to:

- a. Whether Depo Testosterone was and is unsafe for human use;
- b. Whether defendant designed, manufactured and/or marketed Depo Testosterone with knowledge that it was a dangerously defective product;
- c. Whether defendant acted negligently in marketing and selling Depo Testosterone;
- d. Whether defendant conducted, either directly or indirectly, adequate testing of Depo Testosterone;
- e. Whether defendant failed to adequately warn consumers of the adverse health hazards caused by using Depo Testosterone;

- f. Whether defendant falsely and fraudulently misrepresented in their advertisements, promotional materials and other materials, among other things, the safety of using Depo Testosterone
- g. Whether defendant knowingly omitted, suppressed or concealed material facts about the unsafe and defective nature of Depo Testosterone from governmental regulators, the medical community and/or the consuming public;
- h. Whether defendant's post-marketing safety and surveillance system exists, and if so, was designed and implemented in a reasonable manner;
- i. Whether defendant designed and manufactured a drug that was dangerously defective because its use leads to or poses a substantial increased risk of the existence of potentially dangerous side effects, including, but not limited to, heart attack, stroke and blood clots;
- j. Whether defendant knew or should have known that the ingestion of Depo Testosterone leads to or poses a substantial increased risk of side-effects;
- k. Whether defendant continued to manufacture, label, license, market, distribute, promote and/or sell the drug, Depo Testosterone, notwithstanding its knowledge of the drug's dangerous nature and side-effects;
- l. Whether the warnings and information defendant provided with Depo Testosterone was adequate in warning of the potential hazards resulting from its use;
- m. Whether defendant engaged in unconscionable and/or deceptive business practices and conduct;

- n. Whether the Class has been injured by virtue of defendant's negligence, recklessness, and/or unconscionable and/or deceptive business practices and conduct;
- o. Whether ingestion of Depo Testosterone causes an increased risk of side-effects; and,
- p. Whether defendant earned substantial profits as a result of their sale of Depo Testosterone

70. These and other questions of law and/or fact is common to the Class and predominate over any question affecting only individual class members.

71. The claims of the class representatives is typical of the claims of the Class in that the named representatives and the members of the Class ingested Depo Testosterone and was injured thereby.

72. The Plaintiff will fairly and adequately represent and protect the interests of the members of the Class. Plaintiff has retained counsel competent and experienced in complex class actions and products liability litigation. Plaintiff has no known interests which is adverse to the interests of the other members of the Class. The interests of the plaintiff and the Class they seek to represent is aligned because of their ingestion of Depo Testosterone and their consequential increased risk of the existence of the side effects caused by Depo Testosterone.

73. Class certification is also appropriate under Fed.R.Civ.P. Rule 23(b)(3) because common issues of law and fact relative to the design, manufacture and marketing of Depo Testosterone predominate over individual issues. A class action is superior to other available methods for the fair and efficient adjudication of this litigation since individual joinder of all members of the Class is impracticable.

**CAUSES OF ACTION**

**COUNT I**

**(As to AndroDerm Defendants)**

**STRICT PRODUCTS LIABILITY - MANUFACTURING DEFECT**

74. Plaintiff incorporates each paragraph of this Complaint as if set forth fully herein and further alleges as follows.

75. AndroDerm was designed, manufactured, marketed, promoted, sold, and introduced into the stream of commerce by Defendants.

76. When it left the control of Defendants, AndroDerm was expected to, and did reach Plaintiff without substantial change from the condition in which it left Defendants' control.

77. AndroDerm was defective when it left Defendants' control and was placed in the stream of commerce, in that there were foreseeable risks that exceeded the benefits of the products and/or that it deviated from product specifications and/or applicable federal requirements, and posed a risk of serious injury and death.

78. Specifically, AndroDerm was more likely to cause heart attacks, strokes, the development of deep vein thrombosis and/or pulmonary embolism, and death than other similar medications.

79. Plaintiff used AndroDerm in substantially the same condition it was in when it left control of Defendants and any changes or modifications were foreseeable by Defendants.

80. Plaintiff and his healthcare providers did not misuse or materially alter the AndroDerm.

81. As a direct and proximate result of the Plaintiff's use of AndroDerm he suffered serious physical injury, harm, damages and economic loss, and will continue to suffer such harm, damages and economic loss in the future.

82. Defendants is strictly liable to Plaintiff for designing, creating, manufacturing, distributing, selling, and placing AndroDerm into the stream of commerce, and for all damages caused to Plaintiff by his use of AndroDerm because the product was defective.

83. Defendants' actions and omissions as alleged in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which he is entitled under law and such other relief as this Honorable Court deems appropriate.

**COUNT II**  
**(As to DepoTestosterone Defendants)**  
**STRICT PRODUCTS LIABILITY - MANUFACTURING DEFECT**

84. Plaintiff incorporates each paragraph of this Complaint as if set forth fully herein and further alleges as follows.

85. Depo Testosterone was designed, manufactured, marketed, promoted, sold, and introduced into the stream of commerce by Defendants.

86. When it left the control of Defendants, Depo Testosterone was expected to, and did reach Plaintiff without substantial change from the condition in which it left Defendants' control.

87. Depo Testosterone was defective when it left Defendants' control and was placed in the stream of commerce, in that there was foreseeable risks that exceeded the benefits of the products and/or that it deviated from product specifications and/or applicable federal requirements, and posed a risk of serious injury and death.

88. Specifically, Depo Testosterone was more likely to cause heart attacks, strokes, the development of deep vein thrombosis and/or pulmonary embolism, and death than other similar medications.

89. Plaintiff used Depo Testosterone in substantially the same condition it was in when it left control of Defendants and any changes or modifications were foreseeable by Defendants.

90. Plaintiff and his healthcare providers did not misuse or materially alter the Depo Testosterone.

91. As a direct and proximate result of the Plaintiff's use of Depo Testosterone, he suffered serious physical injury, harm, damages and economic loss, and will continue to suffer such harm, damages and economic loss in the future.

92. Defendants is strictly liable to Plaintiff for designing, creating, manufacturing, distributing, selling, and placing Depo Testosterone into the stream of commerce, and for all damages caused to Plaintiff by his use Depo Testosterone because the products was defective.

93. Defendants' actions and omissions as alleged in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which he is entitled under law and such other relief as this Honorable Court deems appropriate.

**COUNT III**  
**(As to the AndroDerm Defendants)**  
**STRICT PRODUCTS LIABILITY – DESIGN DEFECT**

94. Plaintiff incorporates each paragraph of this Complaint as if set forth fully herein and further alleges as follows.

95. AndroDerm was not merchantable and/or reasonably suited to the use intended, and their condition when sold was the proximate cause of the injuries sustained by Plaintiff.

96. Defendants placed AndroDerm into the stream of commerce with wanton and reckless disregard for the public safety.

97. AndroDerm was defective in design in that, when they left Defendants' control, the foreseeable risks of the product exceeded the benefits associated with its design, and it was more dangerous than an ordinary consumer or ordinary healthcare provider would expect.

98. The foreseeable risks associated with AndroDerm's designs include the fact that its designs is more dangerous than a reasonably prudent consumer or healthcare provider would expect when used in an intended or reasonably foreseeable manner.

99. AndroDerm was unsafe, defective, and inherently dangerous conditions, which was unreasonably dangerous to their users and in particular, Plaintiff.

100. AndroDerm was in defective conditions and unsafe, and Defendants knew, had reason to know, or should have known that AndroDerm was defective and unsafe, even when used as instructed.

101. The nature and magnitude of the risk of harm associated with the design of AndroDerm, including the risk of suffering a heart attack, stroke, developing a deep vein thrombosis and pulmonary embolism, and death, is high in light of the intended and reasonably foreseeable use of AndroDerm.

102. The risk of harm associated with the design of AndroDerm is higher than necessary.

103. It is highly unlikely that AndroDerm users would be aware of the risks associated with AndroDerm through either warnings, general knowledge or otherwise, and Plaintiff specifically was not aware of these risks.

104. The designs did not conform to any applicable public or private product standard that was in effect when AndroDerm left the Defendants' control.

105. AndroDerm design is more dangerous than a reasonably prudent consumer would expect when used in their intended or reasonably foreseeable manner as a reversible form of contraceptive. It was more dangerous than Plaintiff expected.

106. The intended or actual utility of AndroDerm is not of such benefit or to justify the risk of heart attack, stroke, deep vein thrombosis, pulmonary embolism and/or death.

107. At the time AndroDerm left Defendants' control, they was both technically and economically feasible to have alternative designs that would not cause heart attack, stroke, deep vein thrombosis, pulmonary embolism and/or death or an alternative designs that would have substantially reduced the risk of these injuries.

108. It was both technically and economically feasible to provide a safer alternative product that would have prevented the harm suffered by Plaintiff.

109. The unreasonably dangerous nature of AndroDerm caused serious harm to Plaintiff.

110. As a direct and proximate result of the Plaintiff's use of AndroDerm which was designed, manufactured, marketed, promoted, sold, and introduced into the stream of commerce



by Defendants, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which he is entitled under law and such other relief as this Honorable Court deems appropriate.

**COUNT IV**  
**(As to Depo Testosterone Defendants)**  
**STRICT PRODUCTS LIABILITY – DESIGN DEFECT**

111. Plaintiff incorporates each paragraph of this Complaint as if set forth fully herein and further alleges as follows.

112. Depo Testosterone was not merchantable and/or reasonably suited to the use intended, and their condition when sold was the proximate cause of the injuries sustained by Plaintiff.

113. Defendants placed Depo Testosterone into the stream of commerce with wanton and reckless disregard for the public safety.

114. Depo Testosterone was defective in design in that, when it left Defendants' control, the foreseeable risks of the product exceeded the benefits associated with its design, and it was more dangerous than an ordinary consumer or ordinary healthcare provider would expect.

115. The foreseeable risks associated with Depo Testosterone's design include the fact that its designs is more dangerous than a reasonably prudent consumer or healthcare provider would expect when used in an intended or reasonably foreseeable manner.

116. Depo Testosterone was unsafe, defective, and inherently dangerous conditions, which was unreasonably dangerous to its users and in particular, Plaintiff.

117. Depo Testosterone was in a defective conditions and unsafe, and Defendants knew, had reason to know, or should have known that it was defective and unsafe, even when used as instructed.

118. The nature and magnitude of the risk of harm associated with the designs of Depo Testosterone, including the risk of suffering a heart attack, stroke, developing a deep vein thrombosis and pulmonary embolism, and death, is high in light of the intended and reasonably foreseeable use of Depo Testosterone.

119. The risks of harm associated with the design of Depo Testosterone are higher than necessary.

120. It is highly unlikely that Depo Testosterone users would be aware of the risks associated with Depo Testosterone through either warnings, general knowledge or otherwise, and Plaintiff specifically was not aware of these risks.

121. The designs did not conform to any applicable public or private product standard that was in effect when Depo Testosterone left the Defendants' control.

122. Depo Testosterone's design is more dangerous than a reasonably prudent consumer would expect when used in their intended or reasonably foreseeable manner. It was more dangerous than Plaintiff expected.

123. The intended or actual utility of Depo Testosterone is not of such benefit or to justify the risk of heart attack, stroke, deep vein thrombosis, pulmonary embolism and/or death.

124. At the time Depo Testosterone left Defendants' control, it was both technically and economically feasible to have alternative designs that would not cause heart attack, stroke, deep vein thrombosis, pulmonary embolism and/or death or an alternative designs that would have substantially reduced the risk of these injuries.

125. It was both technically and economically feasible to provide a safer alternative product that would have prevented the harm suffered by Plaintiff.

126. The unreasonably dangerous nature of Depo Testosterone caused serious harm to Plaintiff.

127. As a direct and proximate result of the Plaintiff's use of Depo Testosterone, which was designed, manufactured, marketed, promoted, sold, and introduced into the stream of commerce by Defendants, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which he is entitled under law and such other relief as this Honorable Court deems appropriate.

**COUNT VI**  
**(As to AndroDerm Defendants)**  
**STRICT PRODUCTS LIABILITY – FAILURE TO WARN**

128. Plaintiff incorporates each paragraph of this Complaint as if set forth fully herein and further alleges as follows.

129. Defendants had a duty to warn Plaintiff and his healthcare providers of the risk of heart attack, stroke, deep vein thrombosis, pulmonary embolism and/or death associated with AndroDerm.

130. Defendants knew, or in the exercise of reasonable care should have known, about the risk of heart attack, stroke, deep vein thrombosis, pulmonary embolism and/or death.

131. Defendants failed to provide warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of heart attack, stroke, deep

vein thrombosis, pulmonary embolism and/or death, in light of the likelihood that their products would cause these injuries.

132. Defendants failed to update warnings based on information received from product surveillance after AndroDerm was first approved by the FDA and marketed, sold, and used in the United States and throughout the world.

133. A manufacturer exercising reasonable care would have updated its warnings on the basis of reports of injuries to men using AndroDerm after FDA approval.

134. When it left Defendants' control, AndroDerm was defective and unreasonably dangerous for failing to warn of the risk of heart attack, stroke, deep vein thrombosis, pulmonary embolism and/or death.

135. Plaintiff used AndroDerm for its approved purpose and in a manner normally intended and reasonably foreseeable by the Defendants.

136. Plaintiff and Plaintiff's healthcare providers could not, by the exercise of reasonable care, have discovered the defects or perceived their danger because the risks were not open or obvious.

137. Defendants, as the manufacturers and distributors of AndroDerm are held to the level of knowledge of an expert in the field.

138. The warnings that were given by Defendants were not accurate or clear, and was false and ambiguous.

139. The warnings that were given by the Defendants failed to properly warn physicians of the risks associated with AndroDerm, subjecting Plaintiff to risks that exceeded the benefits to the Plaintiff. Plaintiff, individually and through his physician, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

140. Defendants had a continuing duty to warn Plaintiff and his prescriber of the dangers associated with its product.

141. Had Plaintiff or his healthcare providers received adequate warnings regarding the risks associated with the use of the AndroDerm, he would not have used it.

142. As a direct and proximate result of the Plaintiff's use of AndroDerm and Plaintiff's reliance on Defendants' representations regarding the character and quality of the products and Defendants' failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which he is entitled under law and such other relief as this Honorable Court deems appropriate.

**COUNT VII**  
**(As to Depo Testosterone Defendants)**  
**STRICT PRODUCTS LIABILITY – FAILURE TO WARN**

143. Plaintiff incorporates each paragraph of this Complaint as if set forth fully herein and further alleges as follows.

144. Defendants had a duty to warn Plaintiff and his healthcare providers of the risk of heart attack, stroke, deep vein thrombosis, pulmonary embolism and/or death associated Depo Testosterone.

145. Defendants knew, or in the exercise or reasonable care should have known, about the risk of heart attack, stroke, deep vein thrombosis, pulmonary embolism and/or death.

146. Defendants failed to provide warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of heart attack, stroke, deep

vein thrombosis, pulmonary embolism and/or death, in light of the likelihood that their products would cause these injuries.

147. Defendants failed to update warnings based on information received from product surveillance after Depo Testosterone was first approved by the FDA and marketed, sold, and used in the United States and throughout the world.

148. A manufacturer exercising reasonable care would have updated its warnings on the basis of reports of injuries to men using Depo Testosterone after FDA approval.

149. When they left Defendants' control, Depo Testosterone was defective and unreasonably dangerous for failing to warn of the risk of heart attack, stroke, deep vein thrombosis, pulmonary embolism and/or death.

150. Plaintiff used Depo Testosterone for its approved purpose and in a manner normally intended and reasonably foreseeable by the Defendants.

151. Plaintiff and Plaintiff's healthcare providers could not, by the exercise of reasonable care have discovered the defects or perceived their danger because the risks was not open or obvious.

152. Defendants, as the manufacturers and distributors of Depo Testosterone, are held to the level of knowledge of an expert in the field.

153. The warnings that were given by Defendants were not accurate or clear, and was false and ambiguous.

154. The warnings that were given by the Defendants failed to properly warn physicians of the risks associated with Depo Testosterone, subjecting Plaintiff to risks that exceeded the benefits to the Plaintiff. Plaintiff, individually and through his physician, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

155. Defendants had a continuing duty to warn Plaintiff and his prescriber of the dangers associated with its product.

156. Had Plaintiff or his healthcare providers received adequate warnings regarding the risks associated with the use of the Depo Testosterone, he would not have used it.

157. As a direct and proximate result of the Plaintiff's use of Depo Testosterone and Plaintiff's reliance on Defendants' representations regarding the character and quality of the products and Defendants' failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which he is entitled under law and such other relief as this Honorable Court deems appropriate.

**COUNT VII**  
**(As to AndroDerm Defendants)**  
**NEGLIGENCE**

158. Plaintiff incorporates each paragraph of this Complaint as if set forth fully herein and further alleges as follows.

159. Defendants had a duty to exercise reasonable and ordinary care in the design, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions, and distribution of AndroDerm into the stream of commerce, including a duty to assure that their products did not pose an undue risk of bodily harm and adverse events, and to properly warn of all risks, and comply with federal requirements.

160. Defendants failed to exercise reasonable and ordinary care in the designs, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions

and distribution of AndroDerm into the stream of commerce in that Defendants knew or should have known that the products caused significant bodily harm and was not safe for use by consumers. Specifically, Defendants failed to properly and thoroughly:

- a. Test AndroDerm before releasing it into the market;
- b. Analyze the data resulting from the pre-marketing tests of AndroDerm;
- c. Conduct sufficient post-market testing and surveillance of AndroDerm; and
- d. Provide appropriate warnings for consumers and healthcare providers including disclosure of the known or potential risks or true or suspected rates of heart attack, stroke, deep vein thrombosis, pulmonary embolism and/or death.

161. Despite the fact that Defendants knew or should have known that their products posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market AndroDerm for use by consumers and continued to fail to comply with federal requirements.

162. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above, including the failure to comply with federal requirements.

163. It was foreseeable that Defendants' products, as designed, would cause serious injury to consumers, including Plaintiff.



164. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

165. Defendants' conduct as described above, including but not limited to their failure to adequately design, test, and manufacture, as well as their continued marketing and distribution of AndroDerm when they knew or should have known of the serious health risks they created and the failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

166. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, and willful and wonton conduct, which warrants the imposition of punitive damages.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which he is entitled under law and such other relief as this Honorable Court deems appropriate.

**COUNT VIII**  
**(As to Depo Testosterone Defendants)**  
**NEGLIGENCE**

167. Plaintiff incorporates each paragraph of this Complaint as if set forth fully herein and further alleges as follows.

168. Defendants had a duty to exercise reasonable and ordinary care in the design, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions, and distribution of Depo Testosterone into the stream of commerce, including a duty to assure that their products did not pose an undue risk of bodily harm and adverse events, and to properly warn of all risks, and comply with federal requirements.

169. Defendants failed to exercise reasonable and ordinary course in the designs, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Depo Testosterone into the stream of commerce in that Defendants knew or should have known that the products caused significant bodily harm and was not safe for use by consumers. Specifically, Defendants failed to properly and thoroughly:

- a. Test Depo Testosterone before releasing it into the market;
- b. Analyze the data resulting from the pre-marketing tests of Depo Testosterone;
- c. Conduct sufficient post-market testing and surveillance of Depo Testosterone; and
- d. Provide appropriate warnings for consumers and healthcare providers including disclosure of the known or potential risks or true or suspected rates of heart attack, stroke, deep vein thrombosis, pulmonary embolism and/or death.

170. Despite the fact that Defendants knew or should have known that their products posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market Depo Testosterone for use by consumers and continued to fail to comply with federal requirements.

171. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above, including the failure to comply with federal requirements.

172. It was foreseeable that Defendants' products, as designed, would cause serious injury to consumers, including Plaintiff.

173. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

174. Defendants' conduct as described above, including but not limited to their failure to adequately design, test, and manufacture, as well as their continued marketing and distribution of Depo Testosterone when they knew or should have known of the serious health risks they created and the failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

175. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, and willful and wonton conduct, which warrants the imposition of punitive damages.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which he is entitled under law and such other relief as this Honorable Court deems appropriate.

**COUNT IX**  
**(As to AndroDerm Defendants)**  
**BREACH OF EXPRESS WARRANTY**

176. Plaintiff incorporates each paragraph of this Complaint as if set forth fully herein and further alleges as follows.

177. Defendants expressly warranted that AndroDerm was safe and effective products for the treatment of low testosterone, and did not disclose the material risks that AndroDerm could cause heart attacks, strokes, deep vein thrombosis, pulmonary embolism and/or death. The representations were not justified by the performance of AndroDerm Members of the consuming public, including consumers such as Plaintiff, and his healthcare providers, was intended third party beneficiaries of the warranty.

178. Plaintiff and his healthcare providers reasonably relied on these express representations.

179. The AndroDerm manufactured and sold by Defendants did not conform to these express representations because they caused serious injury to the Plaintiff when used as recommended and directed, and these risks were not disclosed to Plaintiff or his healthcare providers.

180. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which he is entitled under law and such other relief as this Honorable Court deems appropriate.

**COUNT X**  
**(As to Depo Testosterone Defendants)**  
**BREACH OF EXPRESS WARRANTY**

181. Plaintiff incorporates each paragraph of this Complaint as if set forth fully herein and further alleges as follows.

182. Defendants expressly warranted that Depo Testosterone was safe and effective products for the treatment of low testosterone, and did not disclose the material risks that Depo Testosterone could cause heart attacks, strokes, deep vein thrombosis, pulmonary embolism and/or death. The representations were not justified by the performance of Depo Testosterone.

183. Members of the consuming public, including consumers such as Plaintiff, and his healthcare providers, were intended third party beneficiaries of the warranty.

184. Plaintiff and his healthcare providers reasonably relied on these express representations.

185. The Depo Testosterone manufactured and sold by Defendants did not conform to these express representations because they caused serious injury to the Plaintiff when used as recommended and directed, and these risks was not disclosed to Plaintiff or his healthcare providers.

186. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which he is entitled under law and such other relief as this Honorable Court deems appropriate.

**COUNT XII**  
**(As to AndroDerm Defendants)**  
**BREACH OF IMPLIED WARRANTY**

187. Plaintiff incorporates each paragraph of this Complaint as if set forth fully herein and further alleges as follows.

188. When Defendants designed, manufactured, marketed, sold, and distributed their AndroDerm for use by the Plaintiff, Defendants knew of the use for which they was intended and impliedly warranted the products to be of merchantable quality and safe for such use and that their designs, manufacture, labeling, and marketing complied with all applicable federal requirements.

189. Plaintiff and his physicians reasonably relied upon the Defendants' representations of the products' merchantable quality and that they was safe for their intended use, and upon Defendants' implied warranty, including that they was in compliance with all federal requirements.

190. Contrary to such implied warranty, AndroDerm was not of merchantable quality or safe for their intended use, because the products was defective, as described herein, and they failed to comply with federal requirements.

191. As a direct and proximate result of Defendants' breach of warranty, the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which he is entitled under law and such other relief as this Honorable Court deems appropriate.

**COUNT XIII**  
**(As to Depo Testosterone Defendants)**  
**BREACH OF IMPLIED WARRANTY**

192. Plaintiff incorporates each paragraph of this Complaint as if set forth fully herein and further alleges as follows.

193. When Defendants designed, manufactured, marketed, sold, and distributed their Depo Testosterone for use by the Plaintiff, Defendants knew of the use for which they was intended and impliedly warranted the products to be of merchantable quality and safe for such use and that their designs, manufacture, labeling, and marketing complied with all applicable federal requirements.

194. Plaintiff and his physicians reasonably relied upon the Defendants' representations of the products' merchantable quality and that they was safe for their intended use, and upon Defendants' implied warranty, including that they was in compliance with all federal requirements.

195. Contrary to such implied warranty, Depo Testosterone was not of merchantable quality or safe for their intended use, because the products was defective, as described herein, and they failed to comply with federal requirements.

196. As a direct and proximate result of Defendants' breach of warranty, the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which he is entitled under law and such other relief as this Honorable Court deems appropriate.

**COUNT XIV**  
**(As to AndroDerm Defendants)**  
**FRAUD**

197. Plaintiff incorporates by reference here each of the allegations set forth in this Complaint as though set forth fully herein.

198. Defendants, from the time they first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed AndroDerm and up to the present, willfully deceived Plaintiff by concealing from him, his physicians and the general public, the true facts concerning AndroDerm which the Defendants had a duty to disclose.

199. At all times herein mentioned, Defendants conducted a sales and marketing campaign to promote the sale of AndroDerm and willfully deceived Plaintiff, Plaintiff's physicians and the general public as to the benefits, health risks and consequences of using AndroDerm. Defendants knew of the foregoing, that AndroDerm was not safe, fit and effective for human consumption, that using AndroDerm is hazardous to health, and that AndroDerm have

a serious propensity to cause serious injuries to their users, including but not limited to the injuries Plaintiff suffered.

200. Defendants concealed and suppressed the true facts concerning AndroDerm with the intent to defraud Plaintiff, in that Defendants knew that Plaintiff's physicians would not prescribe AndroDerm, and Plaintiff would not have used AndroDerm, if they were aware of the true facts concerning the dangers.

201. As a result of Defendants' fraudulent and deceitful conduct, Plaintiff suffered injuries and damages as alleged herein.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which he is entitled under law and such other relief as this Honorable Court deems appropriate.

**COUNT XV**  
**(As to Depo Testosterone Defendants)**  
**FRAUD**

202. Plaintiff incorporates by reference here each of the allegations set forth in this Complaint as though set forth fully herein.

203. Defendants, from the time they first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed Depo Testosterone, and up to the present, willfully deceived Plaintiff by concealing from him, his physicians and the general public, the true facts concerning Depo Testosterone, which the Defendants had a duty to disclose.

204. At all times herein mentioned, Defendants conducted a sales and marketing campaign to promote the sale of Depo Testosterone and willfully deceived Plaintiff, Plaintiff's physicians and the general public as to the benefits, health risks and consequences of using Depo Testosterone. Defendants knew of the foregoing, that Depo Testosterone was not safe, fit and



effective for human consumption, that using Depo Testosterone is hazardous to health, and that Depo Testosterone has serious propensity to cause serious injuries to their users, including but not limited to the injuries Plaintiff suffered.

205. Defendants concealed and suppressed the true facts concerning Depo Testosterone with the intent to defraud Plaintiff, in that Defendants knew that Plaintiff's physicians would not prescribe Depo Testosterone, and Plaintiff would not have used Depo Testosterone, if they were aware of the true facts concerning the dangers.

206. As a result of Defendants' fraudulent and deceitful conduct, Plaintiff suffered injuries and damages as alleged herein.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which he is entitled under law and such other relief as this Honorable Court deems appropriate.

**COUNT XVI**  
**(As to AndroDerm Defendants)**  
**NEGLIGENT MISREPRESENTATION**

207. Plaintiff incorporates by reference herein each of the allegations set forth in this Complaint as though fully set forth herein.

208. From the time AndroDerm was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiff, Plaintiff's physicians and the general public, including but not limited to the misrepresentation that AndroDerm was safe, fit and effective for human use. At all times mentioned, Defendants conducted sales and marketing campaign to promote the sale of AndroDerm and willfully deceived Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of AndroDerm.

209. The Defendants made the foregoing representation without any reasonable ground for believing them to be true. These representations was made directly by Defendants, by sales representatives and other authorized agents of Defendants, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject products.

210. The representations by the Defendants was in fact false, in that AndroDerm not safe, fit and effective for human consumption, using AndroDerm is hazardous to health, and AndroDerm have serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiff.

211. The foregoing representations by Defendants, and each of them, were made with the intention of inducing reliance and the prescription, purchase and use of AndroDerm and DepoTestosterone.

212. In reliance of the misrepresentations by the Defendants, and each of them, Plaintiff was induced to purchase and use AndroDerm and Depo Testosterone. If Plaintiff had known of the true facts and the facts concealed by the Defendants, Plaintiff would not have used AndroDerm and Depo Testosterone. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations was made and conducted by individuals and entities that were in a position to know the true facts.

213. As a result of the foregoing negligent misrepresentations by Defendants, Plaintiff suffered injuries and damages as alleged herein.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which he is entitled under law and such other relief as this Honorable Court deems appropriate.

**COUNT XVII**  
**(As to Depo Testosterone Defendants)**  
**NEGLIGENT MISREPRESENTATION**

214. Plaintiff incorporates by reference herein each of the allegations set forth in this Complaint as though fully set forth herein.

215. From the time Depo Testosterone was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiff, Plaintiff's physicians and the general public, including but not limited to the misrepresentation that Depo Testosterone was safe, fit and effective for human use. At all times mentioned, Defendants conducted sales and marketing campaign to promote the sale of Depo Testosterone and willfully deceived Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of Depo Testosterone.

216. The Defendants made the foregoing representation without any reasonable ground for believing them to be true. These representations was made directly by Defendants, by sales representatives and other authorized agents of Defendants, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject products.

217. The representations by the Defendants was in fact false, in that Depo Testosterone is not safe, fit and effective for human consumption, using Depo Testosterone is hazardous to health, Depo Testosterone have serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiff.

218. The foregoing representations by Defendants, and each of them, were made with the intention of inducing reliance and the prescription, purchase and use of Depo Testosterone.

219. In reliance of the misrepresentations by the Defendants, and each of them, Plaintiff was induced to purchase and use of Depo Testosterone. If Plaintiff had known of the true facts and the facts concealed by the Defendants, Plaintiff would not have used Depo Testosterone. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations was made and conducted by individuals and entities that were in a position to know the true facts.

220. As a result of the foregoing negligent misrepresentations by Defendants, Plaintiff suffered injuries and damages as alleged herein.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which he is entitled under law and such other relief as this Honorable Court deems appropriate.

**COUNT XVIII**  
**PUNITIVE DAMAGES ALLEGATIONS**  
**(As to Both Defendants Respectively)**

221. Plaintiff incorporates by reference here each of the allegations set forth in this Complaint as though fully set forth herein.

222. The respective acts, conduct, and omissions of Defendants, as alleged throughout this Complaint was willful and malicious. Defendants committed these acts with a conscious disregard for the rights of Plaintiff and other AndroDerm and Depo Testosterone users and for the primary purpose of increasing Defendants' profits from the sale and distribution of AndroDerm and Depo Testosterone. Defendants' respective outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

223. Prior to the respective manufacturing, sale, and distribution of AndroDerm and Depo Testosterone, Defendants respectively knew that their respective drug was in defective conditions as previously described herein and knew that those who was prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their respective officers, directors, managers, and agents, knew that the medication presented a substantial and unreasonable risk of harm to the public, including Plaintiff and as such, Defendants unreasonably subjected consumers of said drugs to risk of injury or death from using AndroDerm and Depo Testosterone.

224. Despite its knowledge, Defendants, respectively acting through its officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in their respective drugs and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in their drugs. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of their drugs knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

225. Defendants' respective conduct was despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendants with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

WHEREFORE, Plaintiff respectfully requests an award of punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which he is entitled under law and such other relief as this Honorable Court deems appropriate.

**COUNT XIX**  
**(As to Both Defendants)**  
**LOSS OF CONSORTIUM**

226. Plaintiff incorporates by reference here each of the allegations set forth in this Complaint as though fully set forth herein.

227. Donna McGill is the spouse of the Plaintiff and as such, lived and cohabited with him.

228. By reason of the foregoing, Plaintiff's spouse has necessarily paid and has become liable to pay for medical aid, treatment, attendance, and for medications, and will necessarily incur further expenses of a similar nature in the future.

229. By reason of the foregoing, Plaintiff's spouse has been caused, presently and in the future, the loss of his companionship, service and society.

230. As a foreseeable, direct, and proximate result of the wrongful acts and omissions of defendants, plaintiffs was caused to suffer economic damages, including medical and hospital expense, severe and possibly permanent injuries, pain, suffering, and emotional distress.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which she is entitled under law and such other relief as this Honorable Court deems appropriate.

**PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiff, for himself and all others similarly situated, request that this Court enter a judgment against the Defendants and in favor of the plaintiff, on behalf of himself and the members of the Class, and to award the following relief:

- a) An Order requiring the immediate Notification of all individuals in the class of the potential harm from the drugs named either alone or in combination with other drugs;
- b) An Order declaring this action to be proper class action pursuant to Federal Rule of Civil Procedure 23, certifying and establishing an appropriate Class, and finding that plaintiff is a proper representatives of the Class;
- c) An Order declaring the defendant financially responsible for notifying all class members that the drugs named are dangerous and for taking all other actions requested herein; judgment in his favor and against defendant; compensatory damages in an amount in excess of the jurisdictional limit; exemplary and punitive damages in an amount in excess of the jurisdictional limit, where appropriate;
- d) all elements of interest, including but not limited to pre- and post-judgment interest;
- e) all Bill of Costs elements, including attorney fees and expert witness fees;
- f) such other and further relief as the Court may deem just and proper;
- g) trial by a jury on all issues of the case; and,
- h) awarding reasonable attorney fees and costs to plaintiff and the class.

**DEMAND FOR JURY TRIAL**

The Plaintiff hereby demands a trial by jury on all counts and as to all issues.

Respectfully submitted,

/s/ Michael M. Weinkowitz  
Arnold Levin (PA ID 02280)  
Laurence S. Berman (PA ID 26965)  
Michael M. Weinkowitz (PA ID 76033)  
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*Attorneys for Plaintiff*

Dated: 4/11/2014



**DEMAND FOR JURY TRIAL**

Plaintiff demands a trial by jury on all counts and as to all issues.

Respectfully submitted,

/s/ Michael M. Weinkowitz

Michael M. Weinkowitz

Dated: 4/11/2014